

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION)	CASE NO. 1:17-MD-2804
OPIATE LITIGATION)	
)	SPECIAL MASTER COHEN
THIS DOCUMENT RELATES TO:)	
<i>“Track One Cases”</i>)	
)	DISCOVERY RULING NO. 14, PART 8
)	REGARDING PRIVILEGE CLAIMS
)	ON SOMS AUDITS

AGENDA ITEMS 204, 205, 206, 209, 210

During Track One discovery, defendants McKesson, Purdue, AmerisourceBergen, Teva, and Par withheld from discovery as privileged a number of SOMS audits and related communications. Plaintiffs contend these documents must be produced. After the parties met and conferred to reduce the number of disagreements, the Special Master directed the defendants to produce the remaining disputed documents for *in camera* review. The parties have also submitted letter briefs and supporting exhibits. The Special Master, having considered the submissions carefully and reviewed each of the contested documents, rules as follows.

I. Legal Standards.

The Special Master set out the legal standards applicable to attorney-client privilege and the work-product doctrine in *Discovery Ruling No. 14, Part 1* and *Amended Discovery Ruling No.*

14, Part I.¹ The Special Master applied these standards to a SOMS audit in *Discovery Ruling No. 14, Part 5* (“DR 14-5”),² and directed the parties to apply the precepts of that *Ruling* to their SOMS audit documents. Of particular relevance to these *Rulings* is the distinction between legal advice and business advice. As explained in DR 14-5, documents “prepared by a corporation as part of efforts to ensure compliance with federal regulatory agencies . . . and not because of possible litigation, are not protected by work-product doctrine.” *Graff v. Haverhill N. Coke Co.*, 2012 WL 5495514 at *6 (S.D. Ohio Nov. 13, 2012) (quoting *In re Avandia Marketing, Sales Practices and Prods. Liab. Litig.*, 2009 WL 4641707 at *3 (E.D. Pa. Dec. 7, 2009)); *Zigler v. Allstate Ins. Co.*, 2007 WL 1087607 at *1 (N.D. Ohio Apr. 9, 2007) (a “communication is not privileged simply because it is made by or to a person who happens to be an attorney. To be privileged, the communication must have the *primary* purpose of soliciting legal, rather than business, advice.”) (internal quotation marks and citations omitted, emphasis in original); *see also Fed. Trade Comm’n v. Abbvie, Inc.*, 2015 WL 8623076 at *9 (E.D. Pa. Dec. 14, 2015) (“attorney-client privilege does not apply . . . if the client seeks regulatory advice for a business purpose”). This distinction undergirds most of the rulings below.

As a preliminary matter, the Special Master notes that plaintiffs have argued, with respect to three sets of documents addressed in this *Report*, that defendants have waived *wholesale* any privilege or work-product protection by putting the subject matter of the contested documents at issue. Plaintiffs state defendants have made factual assertions or pled affirmative defenses that cannot be fairly evaluated without access to any withheld document that addresses the defendants’ Suspicious Order Monitoring Systems. Although there is Sixth Circuit authority supporting a

¹ See docket nos. 1321 & 1380; *see also* Order at docket no. 1428 (affirming these *Rulings*).

² See docket no. 1498; *see also* Order at docket no. 1553 (affirming this *Ruling*).

broad reading of waiver,³ there are also numerous cases that take a more measured position and hold, as defendants argue, that unless the party asserting privilege has put the *particular* document at issue, it has not waived the privilege.⁴ The Special Master declines to follow the more expansive approach to waiver urged by plaintiffs in the context of these SOMS audits and related documents.

II. Analysis

A. McKesson

1. Attorney-Client Privilege

McKesson has withheld four audit reports, all of which it produced internally. These are referred to herein as the 2008 Audit Report,⁵ the 2012 Audit Report,⁶ the 2013 Audit Report,⁷ and the 2016 Audit Report.⁸ McKesson claims it produced these documents for the purpose of enabling counsel to provide “legal, rather than business advice,”⁹ so they are protected by both attorney-client privilege and the attorney work-product doctrine. The Special Master has reviewed carefully

³ See, e.g., *In re Lott*, 424 F.3d 446, 454 (6th Cir. 2005) (“Litigants cannot hide behind the privilege if they are relying on privileged communications to make their case.”); *United States v. Bilzerian*, 926 F.2d 1285, 1292 (2nd Cir. 1991) (“[T]he privilege may be implicitly waived when defendant asserts a claim that in fairness requires examination of the protected communications.”); *In re Kidder Peabody Secs. Litig.*, 168 F.R.D. 459, 470 (S.D.N.Y. 1996) (“The waiver may be found even if the privilege holder does not attempt to make use of a privileged communication; he may waive the privilege if he makes factual assertions the truth of which can only be assessed by examination of the privileged communication.”).

⁴ See, e.g., *United States v. Ohio Edison Co.*, 2002 WL 1585597 at *3 (S.D. Ohio July 11, 2002) (“[A] party must affirmatively use privileged communications to defend itself or attack its opponent in the action before the waiver rule is applicable.”); *Denman v. Youngstown State Univ.*, 2007 WL 2781351 at *6 (N.D. Ohio Sept. 21, 2007) (“[w]aiver is not likely to be found when the statements alleged to constitute waiver do not disclose the specific contents of a specific communication between client and attorney”).

⁵ MCKMDLPRIV-04271-3, dated October 8, 2008.

⁶ MCKMDLPRIV-04274-5, dated January 24, 2013.

⁷ MCKMDLPRIV-04276-7, dated April 18, 2014.

⁸ MCKMDLPRIV-04278-9, dated October 17, 2016.

⁹ McKesson letter brief, dated April 22, 2019, at 2.

not only the four withheld Audit Reports, but also other roughly-concurrent audit reports McKesson produced in this MDL.

The withheld Reports all address the highly sensitive regulatory matter of Suspicious Order Monitoring Systems (“SOMS”), with a particular focus on controls for threshold monitoring. The concurrent reports McKesson produced in discovery, by contrast, examine more routine regulatory matters, such as the appropriate handling of hazardous materials, inadequate inventory controls that could result in faulty financial reporting, inventory rotation deficiencies that could result in financial loss due to product expiration, delinquent communication with vendors concerning damaged goods, bills of lading, and warehouse cleanliness.¹⁰

Examination of the withheld Reports alongside the produced reports reveals that all the reports concern themselves with regulatory matters. The sensitivity of the SOMS- or CSMP-related¹¹ issues that are the principal focus of the withheld Reports does not change the essential nature of the Reports’ subject matter from compliance/business to legal. Nor is there anything on the face of the withheld Reports that indicates any lawyer is giving or intends to give legal advice pertaining to them. Simply put, the Reports explain a McKesson business function and assess its weaknesses, and are designed for use by compliance personnel to improve that business function.¹² Consequently, the Special Master concludes McKesson has not sustained its burden of establishing that the four withheld Audit Reports are entitled to protection of attorney-client privilege.

¹⁰ See MCKMDL00594928, MCKMDL 00616427

¹¹ McKesson refers to its SOMS as its Controlled Substance Monitoring Program, or CSMP.

¹² See deposition testimony of Scott Villareal, attached as Exhibit 2 to Plaintiffs’ letter brief dated April 29, 2019 at 115:4-11 (“ . . . any audit we conducted, where we found observations where we felt like could be learned from at enterprise level, that we would always share those to inform and educate everybody.”).

2. Attorney Work Product

The Special Master next addresses whether any of the withheld McKesson Reports should be deemed attorney work product.

a. The 2008 and 2013 Audit Report.

McKesson argues that its 2008 and 2013 Audit Reports are protected attorney work product because they were prepared in anticipation of litigation -- namely, an action brought by the DEA. On May 2, 2008, McKesson entered into a settlement agreement with the DEA resulting from non-compliance with DEA regulations. This agreement required McKesson to “maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations.”¹³ McKesson asserts that, “[a]t the time the 2008 and 2013 audit reports were prepared it reasonably anticipated that there could be litigation with the DEA if McKesson did not meet the terms of the 2008 agreement,”¹⁴ which stated that “[a]ny material breach by any McKesson facility of subsections II.1(a-h) of this Agreement may be a basis upon which the DEA can issue an Order to Show Cause seeking revocation of McKesson’s DEA Certificate(s) of Registration for that facility.”¹⁵

This rationale for assigning work-product status to the Audits fails. Any party that enters into an agreement is aware that it might be sued if it materially breaches that agreement. But it does not follow that every subsequent effort by an attorney to assess the party’s conformity with the agreement’s terms is undertaken in anticipation of litigation. The 2008 and 2013 Audits both took place after the 2008 settlement agreement and before the DEA raided McKesson’s Denver

¹³ McKesson letter brief dated April 29, 2019 at 2.

¹⁴ *Id.* at 3.

¹⁵ *Id.*

distribution center in 2013. McKesson does not point to any surrounding circumstances suggesting that, in 2008 or 2013, it reasonably anticipated additional litigation.

McKesson makes a similar argument with respect to the 2014 and 2016 Audit Reports, though the circumstances surrounding their preparation make for a stronger claim for work-product protection. McKesson asserts that, in “March 2013, a large team of DEA agents and investigators executed an Administrative Inspection Warrant (“AIW”) on McKesson’s distribution center in Aurora (Denver), Colorado. . . . This was followed by additional AIWs, subpoenas, and cyclic inspections at numerous other McKesson distribution centers While the DEA and McKesson ultimately reached agreement on the 2017 settlement, the DEA and DOJ were fully prepared to sue McKesson and had threatened to do just that during the multi-year negotiations that led to the 2017 settlement agreement, MOA, and Compliance Addendum.”¹⁶

The intensity of the DEA’s enforcement activity during this period, marked by subpoenas, AIWs, and threats of a lawsuit, do justify the conclusion that the 2014 and 2016 Audit Reports were prepared in anticipation of litigation and are entitled to designation as attorney work product. Accordingly, the Special Master agrees that McKesson’s invocation of work-product protection is appropriate for the 2014 and 2016 Audit Reports, but not for the 2008 and 2013 Audit Reports.

FRCP Rule 26(b)(3)(A) Exception to Work Product Protection

The conclusion that the 2014 and 2016 Audit Reports are work product, however, does not end the inquiry. As set out in DR 14-5, the Sixth Circuit has recognized that an adverse party can discover fact work product “upon a showing of substantial need and an inability to otherwise obtain without material hardship.” *See Toledo Edison Co. v. G.A. Technologies, Inc.*, 847 F.2d 335, 339-40 (6th Cir. 1998). A plaintiff has substantial need if the documents are “sufficiently unique and

¹⁶ *Id.*

important, as compared to other possible sources of the same information, to justify overriding work product protection.” *Carr v. C.R. Bard, Inc.*, 297 F.R.D. 328 at 334 (N.D. Ohio 2014).

Because the CSMP relates to a central issue in this MDL, and because the information contained in the 2014 and 2016 Reports is unique and not otherwise available to plaintiffs, the Special Master concludes that plaintiffs have a substantial need for the 2014 and 2016 Audit Reports and are unable to otherwise obtain the information contained therein without substantial hardship. *See* DR 14-5 at 11-12.

For the foregoing reasons, McKesson must produce the 2008, 2013, 2014, and 2016 Audit Reports.

B. Purdue

Purdue seeks to protect a single 2016 SOMS Audit Report performed by IMS Health–BuzzeoPDMA (“IMS”).¹⁷ Purdue asserts it ordered the Audit to assist its outside counsel, Skadden, Arps, in providing legal advice. But this conclusory assertion flies in the face of evidence offered by plaintiffs indicating that the audit was performed to assist business units within Purdue. Although Skadden’s July 21, 2016 retainer agreement with IMS states it engaged IMS “for the purposes of assisting us in providing legal advice” to Purdue,¹⁸ nothing in the withheld report supports Purdue’s contention that the report was primarily related to Skadden’s provision of legal advice, rather than predominantly for business purposes. The Audit is essentially a business

¹⁷ IMS Audit Report of Purdue Pharma, LLP (the “Audit Report”). Unstamped document provided *in camera*.

¹⁸ Skadden/IMS Letter Agreement and Consulting Agreement dated August 31, 2016. Unstamped document provided *in camera*.

document designed to assist Purdue in enhancing its compliance functions; IMS's work for Purdue was fundamentally to provide business consulting work.

Plaintiffs' submissions further support the conclusion that Purdue's IMS Audit Report is not entitled to attorney-client privilege. Plaintiffs submitted documents indicating that Purdue's *non-attorney* compliance personnel: (1) identified the need to hire an outside consultant,¹⁹ (2) engaged in talks with IMS to consider the value of its services,²⁰ (3) reviewed plans for the scope of IMS's work,²¹ and (4) assigned two non-attorney staff persons to take responsibility for becoming the "Administrator of the Buzzeo SOM system."²² Moreover, the Audit Report itself states that its purpose was "to identify potential regulatory risks and provide potential recommendations to enhance Purdue's computer analysis system, SOM procedures and the firm's overall SOM compliance program."²³ Purdue has not sustained its burden to establish that the IMS Audit Report was primarily for the purpose of providing legal, rather than business, advice. Accordingly, it must be produced.

Purdue has not argued this document is protected attorney work product, and the Special Master concludes it is not.

¹⁹ See document headed "Plans for evaluation of the OMS system for Compliance and Efficinencies [*sic*]." Exhibit 3 to Plaintiffs' May 4, 2019 letter brief.

²⁰ See email from Edward Harris of IMS to Mark Geraci, Rodney Benson, and John Gilbride of Purdue dated May 3, 2016. Exhibit 1 to Plaintiffs' May 4, 2019 letter brief; email from David Rosen (Sales & Marketing) to Giselle Issa (Director, OMS & Records Management) dated July 5, 2016. Exhibit 2 to Plaintiffs' May 4, 2019 letter brief.

²¹ See document headed "Plans for evaluation of the OMS system for Compliance and Efficinencies [*sic*]." Exhibit 3 to Plaintiffs' May 4, 2019 letter brief.

²² See email from Danielle Bacco to Allison Uzar dated February 14, 2017. Exhibit 10 to Plaintiffs' May 4, 2019 letter brief.

²³ Audit Report at 2.

C. Teva.

Teva has submitted for *in camera* review two sets of documents over which it claims attorney-client privilege. The first set (the “2013 Documents”) consists of a 2013 report and six drafts thereof.²⁴ The second set (the “2018 Documents”) consists of two copies of a 2018 audit report and one document setting out a list of questions used in assessing Teva’s SOMS.

1. The 2013 Documents

Teva has claimed as privileged a 2013 report (the “White Paper”)²⁵ and 6 drafts or outlines thereof.²⁶ In their challenge to this claim of privilege, plaintiffs have submitted an email indicating Teva shared the final version of the White Paper with SOMS consultant Ron Buzzeo, by email attachment. Teva sent Buzzeo the email in preparation for a July 16, 2013 meeting, to which Buzzeo was invited, at which the White Paper was to be discussed.²⁷ Plaintiffs assert this email transmission of the White Paper constitutes a waiver of any privilege or work-product protection Teva might claim. The Special Master agrees. *See In re Grand Jury Proceedings Oct 12, 1995*, 78 f.3d 251, 254 (6th Cir. 1996) (a party waives attorney-client privilege “by voluntary disclosure of private communications by an individual or corporation to third parties”); *Davis v. Drake*, 2014 WL 5795554 at *3-4 (N.D. Ohio Nov. 6, 2014) (“The party claiming an attorney-client privilege not only bears the burden of proving that the privilege applies, but must also show that the privilege has not been waived.”). However, Teva need not produce the drafts and is entitled to their return. There is no proof that Teva disclosed any of the drafts to any third party.

²⁴ Teva inadvertently produced these documents and seeks to claw them back.

²⁵ TEVA_MDL_A_06925565.

²⁶ TEVA_MDL_A_01453718, 01453880, 06926279, 06926297, 06926300, 06926318.

²⁷ TEVA_MDL_A_06618645, attached as Exhibit 7 to Plaintiffs’ letter brief dated May 10, 2019.

2. The 2018 Documents

Teva also designated as privileged two copies of a 2018 audit report (the “2018 Report”),²⁹ as well as a document comprised of a brief list of questions used in assessing Teva’s SOMS.³⁰ Both documents are clearly attorney work product, prepared in connection with this MDL, as asserted in Teva’s letter brief to the Special Master dated April 27, 2019.

Plaintiffs argue they are nonetheless entitled to these documents pursuant to Fed. R. Civ. P. 26(b)(3)(A), which allows the discovery of protected fact work product upon a showing of substantial need and an inability to obtain similar information without undue burden. Plaintiffs assert they have a substantial need for this particular SOMS audit and no ability to obtain the underlying information without undue hardship; but plaintiffs offer no evidence in support of this conclusion, simply relying instead on the Court’s November 21, 2018 Order concerning the production of SOMS audits.³¹ Having reviewed the withheld 2018 Report, the Special Master concludes plaintiffs do not have a substantial need for the information contained therein.

Plaintiffs further argue that Teva has waived work product protection by putting the subject matter of the document at issue in this litigation. The Special Master concludes Teva has not waived work-product protection with respect to the 2018 Report. Unlike Cardinal’s “Dendrite Audit” addressed in DR 14-5, Teva’s 2018 Report does not “reflect[] directly and clearly on the truth of” Teva’s factual assertions regarding its SOMS. DR 14-5 at 18.

In sum, Teva must produce the final version of the White Paper, but the Special Master upholds Teva’s designation with respect to the draft versions of the White Paper and also the 2018 Documents.

²⁹ Unstamped documents numbered 8 and 9 on Teva’s Privilege Log, Agenda Item 206C.

³⁰ Unstamped document numbered 10 on Teva’s Privilege Log, Agenda Item 206C.

³¹ Docket. No. 1147 at 1.

D. AmerisourceBergen Drug Company

AmerisourceBergen Drug Company (“ABDC”) has withheld a single, internally-produced audit report dated April 27, 2018 (the “Report”).³² ABDC’s in-house legal department authorized this audit in November 2017 in order to learn about the current operation of ABDC’s Order Monitoring Program (“OMP”).³³ The Special Master concludes the Report is protected attorney work product generated in anticipation of litigation -- namely, lawsuits that became a part of this MDL.

Plaintiffs argue that, despite its status as work product, they are entitled to the Report under Rule 26(b)(3)(A). As was the case with respect to Teva’s work product, and for the same reasons, however, the Special Master concludes plaintiffs have not sustained their burden of showing of substantial need and an inability to obtain similar information without undue hardship. The Report simply is not “sufficiently unique and important, as compared to other possible sources of the same information, to justify overriding work product protection.” *Carr*, 297 F.R.D. at 334.

Plaintiffs further argue that ABDC has waived work-product protection by putting the subject matter of the Report at issue in this litigation. For the same reasons as with Teva’s 2018 Report, the Special Master concludes ABDC has not waived work-product protection with respect to its audit Report. ABDC may withhold the Report as attorney work product.

³² ABDCMDL_PRIV_01718.

³³ See Declaration of Christopher J. Casalenuovo, Assistant General Counsel for AmerisourceBergen Corporation. Attached as Exhibit A to ABDC’s May 3, 2019 letter brief.

E. Par

Par has withheld seven documents from production, claiming attorney-client privilege, but not attorney work product protection. Five of these documents are a 2013 SOMS audit report performed by BuzzeoPDMA (the “Report”), dated January 30, 2013, and four drafts thereof.³⁴ The other two documents are emails discussing the Report.³⁵

Par asserts the Report was “prepared for and provided to Par’s in-house legal counsel, Margaret Richardson . . . Par did not offer to share and did not share the SOM audit or the observations or conclusions of that audit with DEA or any other third party.”³⁶ Par further states that “advice was sought from Par’s in-house legal counsel relating to compliance of Par’s order monitoring processes with applicable laws, and the documents Par has withheld are ‘communications relating to that purpose,’ which are protected from disclosure.”³⁷

Par’s submissions are surprisingly bereft of any argument about the nature of the Report itself. The Report is self-evidently a set of recommendations for enhancements to its SOMS function. In DR 14-5, the Special Master described such recommendations as essentially business/compliance related and concluded that the SOMS audit at issue there was, on that and other grounds, not privileged.³⁸ Par’s bare assertion that in-house counsel requested the Report for the purpose of providing legal advice is unsupported by any evidence. Par’s letter briefs focus

³⁴ PRIV00003315, PRIV00003625, PRIV00003631, PRIV00003648, and PRIV00004380. It is not clear from the documents themselves, nor from Par’s description in its letter brief dated May 6, 2019, which of these documents is the final 2013 Report and which are the drafts.

³⁵ PRIV00003624 and PRIV00003630.

³⁶ Par’s letter brief dated May 6, 2019 at 1.

³⁷ *Id.* at 2.

³⁸ See DR 14-5 at 17 (“the entire purpose of the Dendrite Audit (and all of Dendrite’s work) was to assess and improve Cardinal’s *SOM system*, but ‘to be privileged, the communication must have the *primary* purpose of soliciting legal, rather than business, advice.’”) (quoting *Zigler v. Allstate Ins. Co.*, 2007 WL 1087607 at *1 (N.D. Ohio Apr. 9, 2007) (internal quotation marks omitted, emphasis in original)).

instead on the circumstances surrounding the provision of the Report, emphasizing distinctions between those circumstances and the ones present in DR 14-5. These distinctions merely trim around the edges and do not alter the Special Master's core conclusion that the Par Report, as was the case in DR 14-5, was principally (if not solely) "designed to improve [Par's] business processes."³⁹ Par has not sustained its burden of establishing the existence of attorney-client privilege.

Par's other two withheld documents are similarly not privileged. The first is a January 31, 2013 email attaching the Report, sent from attorney Margaret Richardson (Vice President, Legal) to two non-attorneys -- one of whom forwarded it to several other non-attorney compliance personnel and informed them to "limit sharing the data."⁴⁰ The second is a February 19, 2013 email from non-attorney Jill Connell (VP, Enterprise Distribution and Controlled Substance Management) to several non-attorneys and Margaret Richardson.⁴¹ This email, like the first one, is also benign; it merely informs the group of the agenda for that day's meeting, which was to discuss the Report and its recommendations for making changes to Par's SOMS. Just as the Report is not privileged, these routine emails, primarily among non-attorneys for the purpose of distributing and discussing the SOMS enhancement recommendations of the Report, are not privileged.

For these reasons, Par must produce all of its withheld documents.⁴²

³⁹ DR 14-5 at 17.

⁴⁰ PRIV00003624.

⁴¹ PRIV00003630.

⁴² Because none of the copies or versions of the Report (all dated January 31, 2013) is marked as DRAFT, and because Par's privilege log and submissions do not indicate which is the final Report and which, if any, are drafts, it must produce all withheld copies of the Report.

If any party chooses to object to this ruling, it must do so on or before June 14, 2019.

RESPECTFULLY SUBMITTED,

/s/ David R. Cohen

David R. Cohen
Special Master

Dated: June 9, 2019